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NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/803,724	SIMPSON ET AL.
	Examiner	Art Unit
	ALEX NOGUEROLA	1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-41* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *see (6)*
4) ☐ Interview Summary (PTO-413) Paper No(s) _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS of 08/27/01 and 05/30/02*

Claim Rejections - 35 USC § 112

1. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "electric field" in line 2. There is insufficient antecedent basis for this limitation in the claims 1, 2, and 8. Also, an electric field is not a structural limitation.

Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4/1, 5, 6, 7/1, 8, 10, 11/1, 11/8, 12, 13/1, 13/8, 14/1, 14/8, 15/1, 15/8, 16/1, 16/8, 18-23, 26-31, and 36-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Taylor et al. (US 6,375,817 B1), hereafter "Taylor".

Addressing claim 1, Taylor teaches a micromachined analytical device for at least partially separating the components of a sample (abstract), the analytical device comprising

(a) a first channel (**10** in Figure 4) having a sample reservoir at one end (represented by the blackened circle at the end of the short portion of channel **10**) and a waste reservoir at an opposite end (represented by the blackened circle at the end of the long portion of channel **10**);

(b) a second channel which intersects across the first channel (**12**), the second channel comprising an electrophoretic separation channel (col. 7, ll. 18-22); and

(c) a pressure system adapted to generate a pressure differential across the first channel so as to move a sample from the sample reservoir across the first channel and into an intersection between the first and second channels (col. 6, ll. 59-65; col. 5, ll. 56-63 and col. 14, ll. 29-34).

Addressing claim 4/1, a detector positioned along the second channel is taught (col. 5, ll. 45-47 and col. 13, ll. 47-57).

Addressing claim 5, it should be first noted that the type of sample is intended use that does not further structurally limit the invention of claim 1. In any event a sample including DNA fragments is disclosed (col. 10, ll. 41-46 and col. 11, ll. 23-51).

Addressing claims 6, 11/1, and 11/8, a sieving matrix deposited in the second channel is disclosed (col. 3, ll. 1-5).

Addressing claim 12, acrylamide and polyethylene oxide are disclosed (col. 3, ll. 1-5 and col. 7, ll. 14-16).

Addressing claims 7/1 and 10, Figures 5-7 show capillary tubes for delivering samples to the microfabricated device (also see col. 9, ln. 66 – col. 10, ln. 9).

Addressing claim 8, Taylor teaches an analytical device for at least partially separating the components of a sample (abstract), the analytical device comprising

(a) a sample reservoir (represented in Figure 4 by the blackened circle at the end of the short portion of channel **10**);

(b) a first channel extending from the sample reservoir (**10**);

(c) a second channel which intersects with the first channel (**12**), the first and second channels being in fluid communication (Figure 4);

(d) a pressure differential generator adapted to generate a pressure differential across the first channel (col. 6, ll. 59-65; col. 5, ll. 56-63, and col. 14, ll. 29-34); and

(e) an electric field generator adapted to create an electrical field in the second channel (col. 7, ll. 18-22).

Addressing claims 13/1, 13/8, 14/1, 14/8, 15/1, and 15/8, channel widths of 10 µm to 100 µm are disclosed (col. 8, ll. 36-44).

Addressing claim 16/1 and 16/8, a system comprising a plurality of analytical devices as set forth in claims 1 and 8 on the surface of a single substrate is disclosed (Figure 4).

Addressing claim 18, having the second channels share at least one common electrode is implied by Figure 4, which shows common buffer regions 26 and 27.

Addressing claim 19, having the second channels share at two common electrodes is implied by Figure 4, which shows common buffer regions 26 and 27.

Addressing claim 20, Taylor teaches a method for transporting a sample (abstract) using a device which includes a first channel (**10**) having a sample reservoir at one end (represented in Figure 4 by the blackened circle at the end of the short portion of channel **10**) and a waste reservoir at an opposite end (represented by the blackened circle at the end of the long portion of channel **10**) and a second channel (**12**) which intersects across the first channel, comprising

(a) loading the sample into the sample reservoir (col. 6, ll. 59-60, col. 5, ll. 3-4, and col. 9, ln. 66 – col. 10, ln. 9);

(b) generating a first force in the first channel to move the sample along the first channel (col. 6, ll. 59-65, col. 5, ll. 56-63 and col. 14, ll. 29-34); and

(c) applying a second force in the second channel to move at least a portion of the sample into the second channel, the second force being of a different type than the first force (col. 7, ll. 18-22).

Addressing claim 21, that the first force is a pressure differential and the second force is an electric field is disclosed (col. 6, ll. 59-65; col. 5, ll. 56-63; col. 14, ll. 29-34; and col. 7, ll. 18-22).

Addressing claim 22, electrophoretically separating the sample in the second channel is disclosed (col. 7, ll. 18-22).

Addressing claim 23, loading a plurality of samples in sequence as claimed is implied because reconditioning the device for subsequent analyses is taught (col. 14, ll. 59-64).

Addressing claim 26, stacking the sample plug is taught; that is, compressing it with buffer (col. 8, ll. 1-24).

Addressing claim 27, bubble separation of samples is taught (col. 15, ll. 48-51).

Addressing claim 28, it should be first noted that the type of sample is intended use that does not further structurally limit the invention of claim 20. In any event a sample including

DNA fragments is disclosed (col. 10, ll. 41-46 and col. 11, ll. 23-51) and a sieving matrix deposited in the second channel is also disclosed (col. 3, ll. 1-5).

Addressing claim 29, Taylor teaches a method for analyzing a sample (abstract) using a device which includes (i) a sample reservoir into which the sample is placed (represented in Figure 4 by the blackened circle at the end of the short portion of channel **10**); (ii) a first channel in fluid communication with the sample reservoir and adapted for receiving the sample (**10**), (iii) a second channel which intersects with the first channel and which is adapted to receive at least a portion of the sample (**12**), the first and second channel being connected so as to provide continuous fluid communication between the first and second channels (Figure 4), (iv) a pressure differential generator (col. 6, ll. 59-65; col. 5, ll. 56-63; col. 14, ll. 29-34), and (v) an electric field generator (col. 14, ll. 38-45 and col. 7, ll. 18-22), the method comprising

(a) loading the sample into the sample reservoir (col. 6, ll. 59-60; col. 5, ll. 3-4; and col. 9, ln. 66 – col. 10, ln. 9);

(b) generating a pressure differential in the first channel with the pressure differential generator, the pressure differential acting to move the sample from the sample reservoir into and along the first channel (col. 6, ll. 59-65, col. 5, ll. 56-63 and col. 14, ll. 29-34); and

(c) applying an electric field to the second channel using the electric field generator, the electric field acting to move at least a portion of the sample into the second channel (col. 7, ll. 18-22).

Addressing claim 30, loading a plurality of samples is implied because reconditioning the device for subsequent analyses is taught (col. 14, ll. 59-64). Whether the pressure differential is applied continuously or not will depend on whether samples are to be periodically injected or just a single batch run will be performed. Clearly it is wasteful to continuously apply the pressure differential after all the samples to be analyzed have already been introduced into the second channel.

Addressing claim 31, metered loading of plurality of samples is disclosed (col. 15, ll. 48-51). Whether the pressure differential is applied continuously or not will depend on whether samples are to be periodically injected or just a single batch run will be performed. Clearly it is wasteful to continuously apply the pressure differential after all the samples to be analyzed have already been introduced into the second channel.

Addressing claim 36, Taylor teaches an analytical method for the serial injection of multiple samples using a device which includes (i) a sample reservoir designed to receive the samples (represented in Figure 4 by the blackened circle at the end of the short portion of channel **10**), (ii) a first channel in fluid communication with the sample reservoir and adapted for receiving the samples (**10**), and (ii) a second channel which intersects at an angle with the first channel and is adapted to receive a portion of the samples (**12**), the method comprising

(a) loading multiple samples into the sample reservoir (implied by col. 15, ll. 39-54, which teaches a sample delivery system for metering samples and reagents); and

(b) controllably moving the samples along the first channel and diverting a portion of each into the second channel (col. 6, ll. 59-65, col. 5, ll. 56-63 and col. 14, ll. 29-34).

Addressing claim 37, Taylor teaches stacking the sample plugs, which involves covering sample plugs with buffer that concentrates the components in the sample plugs (col. 8, ll. 1-24).

Addressing claim 38, Taylor teaches separating the sample plugs with air bubbles (col. 15, ll. 48-54).

Addressing claim 39, Taylor teaches stacking the sample plugs, which involves covering sample plugs with buffer that concentrates the components in the sample plugs (col. 8, ll. 1-24), and Taylor teaches separating the sample plugs with air bubbles (col. 15, ll. 48-54).

Addressing claims 40 and 41, pressure differential as a first force and an electric field as a second force is taught (col. 6, ll. 59-65; col. 5, ll. 56-63; col. 14, ll. 29-34; and col. 7, ll. 18-22).

4. Claims 2, 9/2, 11/2, 12, 13/2, 14/2, and 15/2 are rejected under 35 U.S.C. 102(e) as being anticipated by Williams et al. (US 2002/0008029 A1), hereafter "Williams".

Addressing claim 2, Williams teaches a micromachined analytical device for at least partially separating the components of a sample (abstract), the analytical device comprising

(a) a first channel (formed by co-axial channel portions **76** and **78** in Figure 3) having a sample reservoir at one end (**S**) and a waste reservoir at an opposite end (**D**);

(b) a second channel which intersects across the first channel (**74**), the second channel comprising an electrophoretic separation channel (paragraphs [0032] and [0026]); and

(c) an electrokinetic system adapted to electrokinetically move a sample from the sample reservoir across the first channel and into an intersection between the first and second channels (paragraph [0049]).

Addressing claim 9/2, "[t]he reservoirs will generally have volumes in the range of 10 nl to 100 μl" (paragraph [0033]).

Addressing claim 11/2, a sieving matrix deposited in the second channel is disclosed (paragraph [0038]).

Addressing claim 12, the sieving matrices listed by Applicant were known within the art at the time of the invention. It was within the skill in art at the time of the invention to select the appropriate sieving matrix, from those claimed, for the analytes of interest.

Addressing claim 13/2, 14/2, and 15/2, channel widths of between 0.5 μm to 1 mm are disclosed (paragraph [0033]).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 3 is rejected under 35 U S C 103(a) as being unpatentable over Taylor et al. (US 6,375,817 B1), hereafter "Taylor", in view of Nelson et al. (US 6,007,690), hereafter "Nelson".

Addressing claim 3, Taylor teaches a micromachined analytical device for at least partially separating the components of a sample (abstract), the analytical device comprising

(a) a first channel (**10** in Figure 4) having a sample reservoir at one end (represented by the blackened circle at the end of the short portion of channel **10**) and a waste reservoir at an opposite end (represented by the blackened circle at the end of the long portion of channel **10**);

(b) a second channel which intersects across the first channel (**12**), the second channel comprising an electrophoretic separation channel (col. 7, ll 18-22); and

(c) a pressure system adapted to generate a pressure differential across the first channel so as to move a sample from the sample reservoir across the first channel and into an intersection between the first and second channels (col. 6, ll 59-65 and col. 5, ll 56-63).

Taylor does not mention providing an injection interface to the sample reservoir.

Nelson teaches a microfluidic device having an injection interface so that sample may be introduced into the fluidic network (col. 10, ll. 10-16) It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a sample injection interface as taught by Nelson in the invention of Taylor because as taught by Nelson the injection interface will serve as a guide for the injection means and act as a seal (col. 10, ll 10-16).

Claims 9/1, 9/8, 24, 25, and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (US 6,375,817 B1), hereafter "Taylor".

Addressing claim 9/1, Taylor teaches a micromachined analytical device for at least partially separating the components of a sample (abstract), the analytical device comprising

(a) a first channel (**10** in Figure 4) having a sample reservoir at one end (represented by the blackened circle at the end of the short portion of channel **10**) and a waste reservoir at an opposite end (represented by the blackened circle at the end of the long portion of channel **10**);

(b) a second channel which intersects across the first channel (**12**), the second channel comprising an electrophoretic separation channel (col. 7, ll. 18-22); and

(c) a pressure system adapted to generate a pressure differential across the first channel so as to move a sample from the sample reservoir across the first channel and into an intersection between the first and second channels (col. 6, ll. 59-65; col. 5, ll. 56-63 and col. 14, ll. 29-34).

Taylor does not mention the sample size range that the sample reservoir is adapted to receive; however, channel widths of 10 µm to 100 µm with a depth of 0.1 µm to about 1000 µm are disclosed (col. 8, ll. 36-44). Thus, even if having the sample reservoir adapted to receive 1 microliter or less of sample can not be strictly implied, barring evidence to the contrary, such as unexpected results, adapting the sample reservoir to receive 1 microliter or less of sample is just a matter of scaling the sample reservoir to the expected sample volume.

Addressing claim 9/8, Taylor teaches an analytical device for at least partially separating the components of a sample (abstract), the analytical device comprising

(a) a sample reservoir (represented in Figure 4 by the blackened circle at the end of the short portion of channel **10**);

(b) a first channel extending from the sample reservoir (**10**);

(c) a second channel which intersects with the first channel (**12**), the first and second channels being in fluid communication (Figure 4);

(d) a pressure differential generator adapted to generate a pressure differential across the first channel (col 6, ll 59-65; col. 5, ll. 56-63; and col. 14, ll. 29-34); and

(e) an electric field generator adapted to create an electrical field in the second channel (col. 7, ll. 18-22).

Taylor does not mention the sample size range that the sample reservoir is adapted to receive; however, channel widths of 10 μm to 100 μm with a depth of 0.1 μm to about 1000 μm are disclosed (col 8, ll. 36-44). Thus, even if having the sample reservoir adapted to receive 1 microliter or less of sample can not be strictly implied, barring evidence to the contrary, such as unexpected results, adapting the sample reservoir to receive 1 microliter or less of sample is just a matter of scaling the sample reservoir to the expected sample volume.

Addressing claim 24 and 25, Taylor teaches a method for transporting a sample (abstract) using a device which includes a first channel (**10**) having a sample reservoir at one end (represented in Figure 4 by the blackened circle at the end of the short portion of channel **10**) and a waste reservoir at an opposite end (represented by the blackened circle at the end of the long

portion of channel **10**) and a second channel (**12**) which intersects across the first channel, comprising

(a) loading the sample into the sample reservoir (col. 6, ll. 59-60; col. 5, ll. 3-4; and col. 9, ln. 66 – col. 10, ln. 9);

(b) generating a first force in the first channel to move the sample along the first channel (col. 6, ll. 59-65; col. 5, ll. 56-63 and col. 14, ll. 29-34); and

(c) applying a second force in the second channel to move at least a portion of the sample into the second channel, the second force being of a different type than the first force (col. 7, ll. 18-22).

Taylor does not specifically mention whether the sample plugs loaded in sequence are the of the same fluid sample or different fluid samples; however, this these limitations are just obvious alternatives. Subsequent sample plugs will either be from the same sample or form different samples. Sample plugs from the same sample would be run to get an average value for better statistical certainty of any measured values while sample plugs from different samples would be run fro comparison or because information is needed from the different samples.

Addressing claim 32, Taylor teaches a method for analyzing a sample (abstract) using a device which includes (i) a sample reservoir into which the sample is placed (represented in Figure 4 by the blackened circle at the end of the short portion of channel **10**); (ii) a first channel in fluid communication with the sample reservoir and adapted for receiving the sample (**10**), (iii) a second channel which intersects with the first channel and which is adapted to receive at least a

portion of the sample (**12**), the first and second channel being connected so as to provide continuous fluid communication between the first and second channels (Figure 4), (iv) a pressure differential generator (col. 6, ll. 59-65; col. 5, ll. 56-63; col. 14, ll. 29-34), and (v) an electric field generator (col. 14, ll. 38-45 and col. 7, ll. 18-22), the method comprising

(a) loading the sample into the sample reservoir (col. 6, ll. 59-60; col. 5, ll. 3-4; and col. 9, ln. 66 – col. 10, ln. 9);

(b) generating a pressure differential in the first channel with the pressure differential generator, the pressure differential acting to move the sample from the sample reservoir into and along the first channel (col. 6, ll. 59-65; col. 5, ll. 56-63 and col. 14, ll. 29-34); and

(c) applying an electric field to the second channel using the electric field generator, the electric field acting to move at least a portion of the sample into the second channel (col. 7, ll. 18-22).

Taylor does not mention a sample size range; however, the sample volume will largely depend on the amount of sample available and how the sample is to be analyzed. It should be noted that in Taylor channel widths of 10 μm to 100 μm with a depth of 0.1 μm to about 1000 μm are disclosed (col. 8, ll. 36-44). Thus, even if having the sample reservoir adapted to receive 1 microliter or less of sample can not be strictly implied, barring evidence to the contrary, such as unexpected results, adapting the sample reservoir to receive 1 microliter or less of sample is just a matter of scaling the sample reservoir to the expected sample volume.

Addressing claim 33, Taylor teaches a method for analyzing a sample (abstract) using a device which includes (i) a sample reservoir into which the sample is placed (represented in Figure 4 by the blackened circle at the end of the short portion of channel **10**); (ii) a first channel in fluid communication with the sample reservoir and adapted for receiving the sample **(10)**, (iii) a second channel which intersects with the first channel and which is adapted to receive at least a portion of the sample **(12)**, the first and second channel being connected so as to provide continuous fluid communication between the first and second channels (Figure 4), (iv) a pressure differential generator (col. 6, ll. 59-65; col. 5, ll. 56-63; col. 14, ll. 29-34), and (v) an electric field generator (col. 14, ll. 38-45 and col. 7, ll. 18-22), the method comprising

(a) loading the sample into the sample reservoir (col. 6, ll. 59-60; col. 5, ll. 3-4; and col. 9, ln. 66 – col. 10, ln. 9);

(b) generating a pressure differential in the first channel with the pressure differential generator, the pressure differential acting to move the sample from the sample reservoir into and along the first channel (col. 6, ll. 59-65; col. 5, ll. 56-63 and col. 14, ll. 29-34); and

(c) applying an electric field to the second channel using the electric field generator, the electric field acting to move at least a portion of the sample into the second channel (col. 7, ll. 18-22).

Taylor does not mention providing sieving medium in the first channel; however, Taylor teaches providing sieving medium in the second channel (col. 3, ll. 1-5) and causing preliminary separation of the sample in the first channel through the use or appropriate ionic medium in the first channel (col. 7, ln. 54 – col. 8, ln. 24). It would have been obvious to one with ordinary

skill in the art at the time the invention was made to also provide sieving medium in the first channel to cause additional preliminary separation.

Addressing claim 34, acrylamide and polyethylene oxide are disclosed (col. 3, ll. 1-5 and col. 7, ll. 14-16)

Addressing claim 35, Taylor teaches size-based separation using the sieving medium (col. 7, ll. 11-13).

9. Claims 2 and 4/2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 2002/0008029 A1), hereafter "Williams", in view of Nelson et al. (US 6,007,690), hereafter "Nelson.

Addressing claim 2, Williams teaches a micromachined analytical device for at least partially separating the components of a sample (abstract), the analytical device comprising

(a) a first channel (formed by co-axial channel portions **76** and **78** in Figure **3**) having a sample reservoir at one end (**S**) and a waste reservoir at an opposite end (**D**);

(b) a second channel which intersects across the first channel (**74**), the second channel comprising an electrophoretic separation channel (paragraphs [0032] and [0026]); and

(c) an electrokinetic system adapted to electrokinetically move a sample from the sample reservoir across the first channel and into an intersection between the first and second channels (paragraph [0049]).

Williams does not mention providing an injection interface to the sample reservoir.

Nelson teaches a microfluidic device having an injection interface so that sample may be introduced into the fluidic network (col. 10, ll. 10-16). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a sample injection interface as taught by Nelson in the invention of Williams because as taught by Nelson the injection interface will serve as a guide for the injection means and act as a seal (col. 10, ll. 10-16).

Addressing claim 4/2, detection is disclosed (paragraph [0075] of Williams). It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide the detector along the second channel because it is in this channel that the sample will be separated.

10. Claims 16/2, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US 2002/0008029 A1), hereafter "Williams", in view of Taylor et al. (US 6,375,817 B1), hereafter "Taylor".

Addressing claim 16/2, Williams teaches a micromachined analytical device for at least partially separating the components of a sample (abstract), the analytical device comprising

(a) a first channel (formed by co-axial channel portions **76** and **78** in Figure 3) having a sample reservoir at one end (S) and a waste reservoir at an opposite end (**D**);

(b) a second channel which intersects across the first channel (74), the second channel comprising an electrophoretic separation channel (paragraphs [0032] and [0026]); and

(c) an electrokinetic system adapted to electrokinetically move a sample from the sample reservoir across the first channel and into an intersection between the first and second channels (paragraph [0049])

Williams does not mention providing a plurality of analytical devices as set forth in claim 2 on the surface of a single substrate. Firstly, barring evidence to the contrary, providing a plurality of analytical devices as claimed in claim 2 is just duplication of parts for a multiplied effect, which has been held obvious [1] In any event, Taylor teaches a plurality of analytical devices similar device to that of claim 2 on the surface of a substrate (see the rejection of claim 1 as being anticipated under 35 U.S.C. 102 (e) by Taylor and Figure 4 of Taylor), the only difference being a pressure system is used to move sample from the sample reservoir across the first channel and into the intersection of the first and second channels. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a plurality of analytical devices on the surface of a substrate as taught by Taylor in the invention of Williams because then several samples samples can be analyzed simultaneously in a compact system.

Addressing claim 18, having the second channels share at least one common electrode is implied by Figure 4 of Taylor, which shows common buffer regions 26 and 27. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide a

[1] St. Regis Paper Co. v. Bemis Co., Inc., 193 USPQ 8, 11.

common electrode as taught by Taylor in the invention of Williams, such as a ground electrode, because then less material and effort will be required to manufacture the device, especially if many second channels are to be provided. With many second channels, many buffer reservoirs, each having its own electrode would be needed if a common electrode was not used.

Addressing claim 19, having the second channels share at two common electrodes is implied by Figure 4 of Taylor, which shows common buffer regions 26 and 27. It would have been obvious to one with ordinary skill in the art at the time the invention was made to provide common electrodes as taught by Taylor in the invention of Williams, if the same voltage potential is to be applied to all of the second channels, because then less material and effort will be required to manufacture the device, especially if many second channels are to be provided. With many second channels, many buffer reservoirs, each having its own electrode would be needed if a common electrodes were not used.

Notice of References cited by the Examiner

11. If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that the copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy

of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

Allowable Subject Matter

12. Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 17: in Taylor and in Williams as modified by Taylor the waste wells are separate; that is, a common waste reservoir is not disclosed. To create a common waste well from the waste wells in Figure 4 of Taylor would require a significant modification of the basic layout of the channels;

14 Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1042.

Alex Noguerola
Alex Noguerola
6/29/03
Primary Examiner
TC1753